

TAB 340

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL
INDUSTRY AVERAGE WHOLESALE
PRICE LITIGATION

THIS DOCUMENT RELATES TO:

*United States of America ex rel. Ven-a-
Care of the Florida Keys, Inc. v. Dey,
Inc., et al.*, Civil Action No. 05-11084-
PBS; and

*United States of America ex rel. Ven-a-
Care of the Florida Keys, Inc. v.
Boehringer Ingelheim Corp., et al.*, Civil
Action No. 07-10248-PBS

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)
)
) MDL No. 1456

) Master Case No. 01-12257-PBS

) Subcategory Case No. 06-11337-PBS

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)
) Hon. Patti B. Saris
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)

DECLARATION OF ROBIN KREUSH STONE

I, Robin Kreush Stone, do hereby declare as follows:

1. I am currently employed by Palmetto as the Manager of the Medicare Pricing Unit. I have personal knowledge of the matters stated in this declaration.
2. I testified in deposition in the above-captioned cases on February 28 and 29, 2008.
3. From 1993 to approximately June 2007, Palmetto GBA was the Durable Medical Equipment Carrier (DMERC) for Region C, serving: Alabama, Arkansas, Colorado, Florida, Georgia, Kentucky, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, Virgin Islands. I

understand that the time period relevant to the above-captioned cases is 1996 through 2003. I generally confine my observations herein to that period.

4. From 1996 to 2002 I held the position of Business Analyst Lead. My responsibilities in that position included providing oversight and training of DMERC pricing analysts performing the DMERC drug pricing updates. In 2002, I became Manager over the Medicare Pricing Unit. My responsibilities were the same with the added managerial requirements.

5. I am familiar with the pricing arrays prepared and used by Palmetto GBA to determine allowable amounts for ipratropium bromide inhalation solution during the period 1996 through December 31, 2003. I identified those arrays in Exhibit Abbott 522 to my deposition, at pages 43-44 (J7645) and pages 62-67 (K0518/J7644) of the exhibit.¹ The arrays were prepared either by me or by members of my staff and reviewed by me. Attached as Exhibit A is a list of the Palmetto arrays for these HCPCS codes that I identified and their Bates-stamp numbers or identifying pathways.

6. In Palmetto's DME pricing arrays for J7644, Palmetto generally classified the Roxane Ipratropium Bromide NovaPlus products as brands. These products were

¹ Except that in Exhibit Abbott 522 I mistakenly stated that no array was located for K0518 for the third quarter of 1997. In fact, the Palmetto array for this quarter is reproduced at AWQ037-0644. Also, in certain quarters (2000 Q1 - Q3, and 2003 Q3 & Q4) Palmetto did not use the precise fees for the KQ modifier shown in the K0518/J7644 arrays but instead used fees based on fees for J7051 agreed upon in consultation with other DMERCs. Finally, I note that the electronic arrays for 2000 Q1, Q2, and Q3 include an Alparma product (in blue font), but this product was not included in the fee calculation.

classified as brands from the first quarter ("Q1") of 2001, when they first appeared in our arrays, through 2003 Q4. For one quarter, 2003 Q2, I am unable to determine with certainty whether they were treated as brands or generics in the fee calculation.

7. In HCFA Transmittal No. AB-98-76, a copy of which is attached to this declaration as Exhibit B, the Health Care Finance Administration (now CMS) instructed carriers that, for a multiple source drug or biological, AWP is equal to the lesser of the median AWP of all the generic forms of the drug or biological or the lowest brand name product AWP. The Transmittal stated, "A 'brand name' product is defined as a product that is marketed under a label name that is other than the generic chemical name for the drug or biological."

8. Palmetto classified products as brands or generics based on the product name. If the product name differed from the chemical name, we considered it a brand. This was the case with NovaPlus. Because this product had the trade name "NovaPlus" added to the chemical name, we considered it a "brand" product.

9. In pricing drugs other than ipratropium bromide during the relevant time period, Palmetto generally classified other products having the "NovaPlus" name as brands. Attached as Exhibit C is a collection of Palmetto arrays that treat NovaPlus products as brands.

10. Palmetto obtained pricing data, including AWP, from the Red Book during the relevant time frame. Prior to approximately 1999, Palmetto used the annual

printed Red Book, plus printed monthly updates. At some point Palmetto began obtaining electronic pricing data from quarterly CD-ROMS published by the Red Book. By 2001 Q1 (the first quarter when the Roxane NovaPlus products appear in the arrays for ipratropium bromide), Palmetto was using the quarterly Red Book CD-ROMS. I can tell this from looking at the pricing array at AWQ037-0038 (attached as Exhibit D).

11. During the period 2001 Q1 through 2002 Q4 or 2003 Q1, Palmetto used the quarterly Red Book CD-ROM to determine whether to treat a drug product as a brand or generic. In approximately 2002 Q4 or 2003 Q1 Palmetto began downloading Red Book data via Red Book's internet-based service and used that data. Palmetto would not have consulted the hard copy printed Red Book publication during the period 2001 Q1 through 2003 Q4 for purposes of determining whether a product was a brand or generic. The electronic CD-ROM version of the Red Book and the internet-based service had different capitalization and typeface conventions as compared to the printed Red Book. We determined whether the product was a brand or generic based on the name of the product.

12. With regard to the Palmetto array for 2003 Q2, a person unfamiliar with the Palmetto database that was in use at the time might conclude from that document that Palmetto treated NovaPlus as a generic product. A copy this array is attached as Exhibit E. The column at the far right of the array, entitled "otype," shows either a "B" or "G," which someone unfamiliar with the originating database might think mean "brand" and "generic," respectively. However, that is not a correct interpretation of the column. That

column indicates whether the fee for the particular HCPCS code was calculated on the basis of the price of a brand or on the basis of the median of the generics; it does not indicate whether the particular drug product was treated as a brand or generic in the calculation.

13. This is illustrated in Exhibit D (the 2001 Q2 array). In Exhibit D, the second column from the left, under the heading "Brand," is the column that specifies whether the product is treated in the calculation as a brand ("Y") or generic ("N"). And the column to the far right, under the heading "typ," indicates that the allowed fee for J7644 was based on the median of the generic forms of the drug.

14. Exhibit E does not include the "Brand" column and does not show whether the Roxane NovaPlus products were treated by Palmetto as a brand or a generic in calculating the fee. I am unable to determine with confidence how in fact they were treated. Palmetto was experiencing difficulties around that time changing to a different electronic system for calculating fees, and in the absence of documentation, I am uncertain how the Roxane NovaPlus was treated. The fact that it was consistently treated as a brand before and after 2003 Q2, and the fact that I am unaware of any reason why we would have changed our normal treatment of this product, suggests that we treated it as a brand. But I am unable to say this with confidence.

15. During the relevant time period, Palmetto published on a quarterly basis DMERC Medicare Advisories containing information regarding the policies and

practices of Palmetto in its Medicare administration work. The other DMERCs similarly published quarterly advisories. Attached as Exhibit F are selected pages of a Palmetto Medicare Advisory for the Summer of 1999. Page 53 gives an update on drug fees for claims processed after April 1, 1999, and states, "The Region C Drug Fee Schedule is based on the lesser of the median average wholesale price (AWP) of the generic forms or the lowest brand name product AWP." The Medical Advisory also invited concerned persons to contact Palmetto with questions, and provided contact information for ombudsmen who could answer questions. The Advisory also provided information about Palmetto's web site. That web site provided on-line access to the Palmetto Provider Manual.

16. In selecting which NDCs were covered under a particular HCPCS code, I generally did not select drugs with special packaging or convenience items such as flip-top vials, carpu-jets, tubes and others because such items are not considered necessities and typically inflate the price.

17. I have reviewed materials indicating that two ipratropium bromide inhalation solution products manufactured by Zenith Goldline appeared in the Red Book in or around 2000. These products have a "P.F." label, which means Preservative Free. I did not include these two Zenith Goldline products in the arrays for ipratropium bromide pursuant to the policy described above because Preservative Free products often utilized special packaging which tended to increase the price.

I swear under penalty of perjury that the foregoing statements are true and correct.

Robin Kreush Stone
Robin Kreush Stone

Executed this 23 day of July, 2009